

Claims

1. A purified nucleic acid sequence encoding a homologue of human interleukin 10 (IL-10), wherein said IL-10 homologue is expressed during the latent phase of infection by a virus of the herpesviridae group.

5 2. The nucleic acid of claim 1, wherein said nucleic acid sequence is as set forth in SEQ ID NO:1.

3. The nucleic acid of claim 1 or 2 wherein the virus of the herpesviridae group is selected from the group consisting of: Epstein-Barr virus, human herpesvirus (HHV)-6, HHV-7, HHV-8, varicella zoster virus, herpes simplex type 1 and type 2 virus and
10 cytomegalovirus.

4. A homologue of human interleukin 10 (IL-10) polypeptide, wherein said IL-10 homologue is expressed during the latent phase of infection by a virus of the herpesviridae group.

5. The IL-10 homologue of claim 4, wherein said homologue is the product of
15 alternative splicing of the primary RNA transcript.

6. The IL-10 homologue of claim 4 or 5, wherein said IL-10 homologue is from the UL111.15A region of the cytomegalovirus genome.

7. The IL-10 homologue of any one of claims 4-6, wherein said IL-10 homologue has the amino acid sequence as set forth in SEQ ID NO:10, or the amino acid
20 sequence as set forth in SEQ ID NO:10 including one or more conservative amino acid substitutions.

8. A vector comprising a nucleic acid sequence in accordance with any one of claims 1 to 3, or a nucleic acid encoding the polypeptide of any one of claims 4 to 7.

9. A recombinant host cell comprising the nucleic acid sequence in accordance
25 with any one of claims 1 to 3 or the vector in accordance with claim 8.

10. A recombinant host cell capable of expressing the polypeptide of any one of claims 4 to 7.

11. An isolated ligand that selectively binds to the polypeptide of any one of claims 4 to 7.

12. The ligand of claim 11, wherein said ligand is an antibody.

13. A method of identifying a compound that interacts with the polypeptide of any one of claims 4 to 7, the method comprising the steps of:

(a) contacting a candidate compound with the polypeptide under conditions suitable to permit interaction of the candidate compound to the polypeptide thereof; and

(b) detecting the interaction between the candidate compound and the polypeptide.

14. The method of claim 13, wherein said interaction is detected by adding a labelled substrate and measuring a change in the labelled substrate.

5 15. A method of identifying a compound that binds to the polypeptide of any one of claims 4 to 7, the method comprising the steps of:

(a) contacting a candidate compound with the polypeptide; and

(b) assaying for the formation of a complex between the candidate compound and the polypeptide.

10 16. The method of claim 15, wherein said assay for the formation of a complex be selected from the group consisting of: a competitive binding assay, a two-hybrid assay or an immunoprecipitation assay.

17. A method of screening for a compound that modulates the activity of the polypeptide of any one of claims 4 to 7, the method comprising the steps of:

15 (a) contacting the polypeptide with a candidate compound under conditions suitable to enable interaction of the candidate compound to the polypeptide; and

(b) assaying for activity of the polypeptide.

18. The method of claim 17, wherein said assay for activity of the polypeptide comprises adding a labelled substrate and measuring a change in the labelled substrate.

20 19. A method of diagnosing a disease state, or predisposition to a disease state, in a subject, the method comprising the steps of:

(a) obtaining a biological sample from the subject; and

(b) assaying for expression of the polypeptide of any one of claims 4 to 7 in the sample.

25 20. The method of claim 19, wherein said assay for the expression of the polypeptide comprises contacting the biological sample with a compound capable of interacting with the polypeptide such that the interaction can be detected.

21. The method of claim 19 or 20, wherein the compound capable of selectively interacting with the polypeptide is an antibody or fragment thereof.

30 22. A method of identifying an agent which is an inhibitor of infection by a virus of the herpesviridae group, the method comprising contacting a cell or cell extract with one or more candidate agents, determining whether there is a change in the activity of a polypeptide of any one of claims 4 to 7 and thereby determining whether the agent is an inhibitor of a virus of the herpesviridae group.

23. The method of any one claims 13 to 22, wherein said viruses of the herpesviridae group are selected from the group consisting of: Epstein-Barr virus, human herpesvirus (HHV)-6, HHV-7, HHV-8, varicella zoster virus, herpes simplex type 1 and type 2 and cytomegalovirus.

5 24. A method of identifying an agent suitable for use in the treatment or prevention of a disease state in a subject, the method comprising:

- (a) obtaining a biological sample from the subject,
- (b) contacting the sample with a candidate agent,
- (c) determining whether there is a change in the activity of the polypeptide of any

10 one of claims 4 to 7, and

(d) thereby determining whether the agent is suitable for use in the treatment of the disease state.

25. A method for treating or preventing a disease state in a subject, the method comprising administering to the subject a therapeutically effective amount of the ligand of claim 11 or 12 or a compound identified by the method of any one of claims 13 to 24.

26. A kit comprising the nucleic acid sequence in accordance with any one of claims 1 to 3 or the polypeptide of any one of claims 4 to 7, or the ligand of claim 11 or 12.

27. The kit of claim 26, wherein the ligand is an antibody.

20 28. A method for screening a subject for infection by a virus of the herpesviridae group, the method comprising:

- (a) obtaining a biological sample from said subject;
- (b) contacting said sample with the ligand of claim 11 or 12, and
- (c) detecting the presence of ligand selectively bound to the polypeptide of any

25 one of claims 4 to 7.

29. The method of claim 28, wherein the biological sample is a plasma or cell sample.

30. A method for screening a subject for infection by a virus of the herpesviridae group, the method comprising:

- (a) obtaining a biological sample from said subject;
- (b) contacting said biological sample from said subject with the nucleic acid sequence of any one of claims 1 to 3; and

(c) detecting the presence or absence of hybridisation between the nucleic acid sample of said biological subject and the nucleic acid sequence of any one of claims 1 to

35 3.

31. A method for screening a biological sample for infection by a virus of the herpesviridae group, the method comprising:

- (g) obtaining a biological sample from said sample;
- (h) contacting said biological sample from said subject with the nucleic acid sequence of any one of claims 1 to 3; and
- (i) detecting the presence or absence of hybridisation between the nucleic acid sample of said biological sample and the nucleic acid sequence of any one of claims 1 to 3.

32. The method of claim 30 or 31, wherein the nucleic acid is capable of selectively hybridising to the nucleic acid encoding the IL-10 homologue expressed during the latent phase of infection by a virus of the herpesviridae group.

33. The method of any one of claims 30 to 32, wherein the nucleic acid sequence corresponds to any one of SEQ ID Nos:2-9.

34. A method for screening a biological sample for infection by a virus of the herpesviridae group, the method comprising:

- (i) contacting said biological sample with the ligand of claims 11 or 12, and
- (ii) detecting the presence of the ligand selectively bound to the polypeptide of any one of claims 4 to 7.

35. The method of claim 34, wherein said ligand is an antibody.

36. The method of claim 34 or 35, wherein the sample is selected from the group consisting of: blood, bone marrow or organ(s) or spinal fluid.

37. The method of any one of claims 32 to 36, wherein the sample is intended to be used in a subject selected from the group consisting of: transplant recipients (bone marrow, stem cell or solid organ), subjects undergoing immunosuppression therapy and immunocompromised subjects.

38. The method of claim 37, wherein the immunocompromised subject is a subject suffering from acquired immune deficiency syndrome (AIDS) or diagnosed as infected with human immunodeficiency virus (HIV).

39. A method of immunosuppression in a subject, said method comprising administering a therapeutically effective amount of the polypeptide of any one of claims 4 to 7.

40. The method of any one of claim 24 to 39, wherein the viruses of the herpesviridae group is selected from the group consisting of: Epstein-Barr virus, human

herpesvirus (HHV)-6, HHV-7, HHV-8, varicella zoster virus, herpes simplex type 1 and type 2 and cytomegalovirus.

41. A vaccine, wherein said vaccine comprises a nucleic acid molecule of any one of claims 1 to 3, or a polypeptide of any one of claims 4 to 7, or a ligand of claim 11 or 12, together with a pharmaceutically acceptable carrier, adjuvant and/or diluent.

42. A method for inducing an immune response in a vertebrate against disease associated with infection by a virus of the herpesviridae group, comprising administering to said vertebrate an immunologically effective amount of the polypeptide of any one of claims 4 to 7, or a ligand of claim 11 or 12, or a vaccine of claim 41.

43. A method for the treatment and/or prophylaxis of disease associated with infection by a virus of the herpesviridae group in a vertebrate, wherein said method comprises administering a therapeutically effective amount of the polypeptide of any one of claims 4 to 7, or a ligand of claim 11 or 12, or the vaccine of claim 41.

44. The method of claim 42 or 43, wherein the polypeptide or ligand is simultaneously or sequentially administered with cytokines.

45. The method of claim 44, wherein the cytokines are selected from the group consisting of: G-CSF, GM-CSF and interleukins.

46. A method of cleansing a biological sample of infection by a virus of the herpesviridae group, the method comprising:

- (a) contacting said biological sample with the ligand of claim 11 or 12,
- (b) detecting the presence of the ligand bound to a cell expressing the polypeptide of any one of claims 4 to 7, and
- (c) removing said cell to which said ligand binds.

47. The method of claim 46, wherein the detection step (b) is an intracellular staining assay.

48. The method of claim 47, wherein the cells identified are then be removed from a mixed cell population by flow cytometry.

49. The method of any one of claims 19 to 48, wherein the disease state is one arising from infection by a virus of the herpesviridae group.

50. The method of claim 49, wherein the disease is selected from the group consisting of: Epstein-Barr virus, human herpesvirus (HHV)-6, HHV-7, HHV-8, varicella zoster virus, herpes simplex type 1 and type 2 and cytomegalovirus.

51. A cleansed biological sample prepared in accordance with the method of any one of claims 46-50.

52. A method of diagnosis of infection of a subject by a virus of the herpesviridae group, the method comprising:

(a) contacting a biological sample of the subject with the ligand of claim 11 or 12,

5 (b) detecting the presence of the ligand thereof selectively bound to the polypeptide of any one of claims 4 to 7.

53. A method of diagnosis of infection of a subject by a virus of the herpesviridae group, the method comprising:

(a) obtaining a biological sample from said subject;

10 (b) contacting said biological sample from said subject with the nucleic acid sequence of any one of claims 1 to 3; and

(c) detecting the presence or absence of hybridisation between the nucleic acid sample of said biological sample and the nucleic acid sequence any one of claims 1 to 3.